\*

Office de la propriété intellectuelle du Canada

Canadian Intellectual Property 
Office

15 MAY

PCTACA 03/00604型 N. 2008 15·05·03

Un organisme d'Industrie Canada An Agency of Industry Canada 074

Bureau canadien

des brevets

Certification

La présente atteste que les documents ci-joints, dont la liste figure ci-dessous; sont des copies authentiques des documents déposés au Bureau des brevets Canadian PECD 5 JUN 2003

Compariso PCT

Certification

This is to certify that the documents attached hereto and identified below are true copies of the documents on file in the Patent Office.

Certified to be a true and correct copy of International Application No: PCT/CA02/00638, filed April 30, 2002

#### PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

Agent cerdificateur/Certificing Officer

May 15, 2003

**Canadä** 

(CIPO 68)



10 .

15

20

25

30

## METHOD AND APPARATUS FOR RECONSTRUCTING BONE SURFACES DURING SURGERY

#### FIELD OF THE INVENTION

The invention relates to the field of computer-assisted surgery or imageguided surgery. More specifically, it relates to the reconstruction of the surface of a bone during surgery.

### **BACKGROUND OF THE INVENTION**

As technology allows us to advance in the field of computer-aided surgery, such systems are becoming more specialized and refined. The advances made for orthopedic surgery are particularly impressive. These systems allow surgeons to prepare for surgery by viewing 3D models of patients' anatomy that were reconstructed using pre-operative images such as scans and x-rays. Virtual planning markers can be inserted into three-dimensional images at any sites of interest and the ideal implant or prosthesis can be designed for a specific patient by constructing virtual implant models and simulating the results with the reconstructed model.

Furthermore, during surgery, many surgical instruments are now tracked and can be displayed on the reconstructed 3D models to provide surgeons with a reference as to where they are within a patient's body. This is a precious asset in surgeries that involve delicate procedures that allow the surgeon very little room to maneuver. Unfortunately, this feature can only be taken advantage of when a 3D reconstruction of the patient's structure has been made. This is done preoperatively using various imaging technologies and can become quite time-consuming for a surgeon.

However, it is desirable to cut down the pre-operative time a surgeon must spend to prepare a surgery. It is also desirable to develop an application that can use other media than Computer-Tomographic (CT) scans, when these are not available.

Moreover, since it is advantageous to provide a surgeon with visual confirmation of the tasks he is performing during the surgery, there is a need to develop a CT-less intra-operative bone reconstruction system.

10

15

20

25

30

## SUMMARY OF THE INVENTION

Accordingly, an object of the present invention is to reduce pre-operative time in surgical procedures.

Another object of the present invention is to reduce the time of instrumentation calibration in surgical procedures.

A further object of the present invention is to provide a simple CT-less system to use for simple surgical cases that can be used in combination with a CT-based system for difficult surgical cases.

Yet another object of the present invention is to optimize the placement of an implant or prosthesis in knee replacement operations in order to extend the lifetime of the implant to its maximum.

According to a first broad aspect of the present invention, there is provided a method for intra-operatively presenting an approximate model of an anatomical structure by collecting a cloud of small surfaces.

Preferably, the cloud of small surfaces is gathered with a registration pointer having an adapted tip capable of making contact with the surface of an anatomical structure and registering the normal at the point of contact.

According to a second broad aspect of the present invention, there is provided a system that takes a collection of points and displays an approximate model of a surface of an anatomical structure.

According to a third broad aspect of the present invention, there is provided a method for placing a positioning guide for total knee replacement orthopedic surgery, the method comprising: locating the center of the femoral head, calculating the mechanical axis, digitizing the medial epicondyles, calculating the epicondylar axis, and calculating the planes required to place the cutting guide.

According to a fourth broad aspect of the present invention, there is provided a method for achieving a symmetric flexion and extension gap to obtain stability in flexion and extension. The method comprises cutting the tibia, recording the tibial cut, applying pressure to the joint to allow the bones to regain their original position, measuring the spacing between the femur and tibia while in extension, measuring the spacing between the femur and tibia while in flexion, and computing the distal cut thickness.

10

15

20

25

30

## BRIEF DESCRIPTION OF THE DRAWINGS

These and other features, aspects and advantages of the present invention will become better understood with regard to the following description and accompanying drawings wherein:

- FIG. 1 is a flowchart of the real time reconstruction of a bone model;
- FIG. 2 shows the center of the femoral head and the mechanical axis;
- FIG. 3 shows the epicondyles and the epicondylar axis;
- FIG. 4 shows the mosaic reconstruction of a bone;
- FIG. 5 shows the reconstructed bone after morphing;
- FIG. 6 shows the placing of the cutting guide;
  - FIG. 7 is a diagram of a registration tool with an adaptive tip; and
  - FIG. 8 is a diagram describing the soft tissue and gap balancing.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purpose of this description, a total knee replacement surgery will be used to demonstrate the invention. However, it can be appreciated that the invention can be used to reconstruct the surface of any anatomical structure in a body.

Figure 1 is a flowchart describing the steps used to reconstruct the femur bone during surgery. The first step is to locate the center of the femoral head 20. This point will be used in calculating the mechanical axis. Also needed to calculate the mechanical axis is locating the entrance point of the mechanical axis 21. This point is in the notch found at the exposed end of the femur bone. The surgeon attempts to locate this point by physically palpating the area and once the center is located, this point is digitized by the registration tool and recorded in memory of the system. The next step involves locating the summits of the epicondyles 22. This is also done by the surgeon palpating the two epicondyles on the bone and locating the summits. These two points are then digitized using the registration tool and kept in memory. These three steps allow for the real-time reconstruction of a model of the femur bone 23. Each of these steps will be described in more detail below.

The large sphere in figure 2 represents the center of the femoral head. Kinematics are used to locate the center of the femoral head by rotating the femur

10

15

20

25

30

bone in a circular motion. The pattern of the rotation is registered and the center of rotation is identified as the center of the femoral head. In order for the movement of the bone to be registered, a position sensor must be placed on the bone and a reference is be placed elsewhere on the body, such as on the pelvis bone in case the hip moves. Each movement of the bone with respect to its reference can them be identified in a position tracking system. The center of the sphere, which appears on the screen of an output device, is kept in memory. A registration tool is then used to digitize the entrance point (see figure 5) of the mechanical axis in the femur bone. A grid (not shown) can help the surgeon locate the entry point of the mechanical axis. A stretchable line that originates at the center of the sphere and moves with the registration tool represents the mechanical axis. This feature allows the user to correct the location of the femoral mechanical axis by clicking on the mechanical entrance point and changing its position. This axis is used as the main axis of the reference system.

The next operation is the digitizing of the epicondyles, as can be seen in figure 3. Two points are used to describe a 3D axis by digitizing the epicondyles using the registration tool. The line formed between the epicondyles represents the epicondylar axis. The user can easily modify the two endpoints at any moment. The epicondylar axis is used as the second axis of the reference system.

The surface model reconstruction is a process that allows the user to digitize small surfaces instead of points only. These surfaces can be small circles, as can be seen from figure 4. The small circle is physically present on the tip of the registration tool as a small, flat disc. The size of the disc (radius) is chosen as a compromise between accuracy and time. It is counter-productive to ask a surgeon to take hundreds of points when digitizing the surface of a bone. However, the more points taken, the better the representation of the bone and the more accurate the model. The size can also vary depending on the morphology of the bone surface, affecting the precision of the tool. For example, the disc could cover an area of 1cm². The disc must be flat on the surface to register as much surface as possible. The tool also registers the normal at the point of contact between the flat disc surface and the bone. When each digitized surface has been registered, an approximate model is displayed on an output device. The model is formed as a mosaic of circular surfaces. This reconstruction is done in real time.

15228-16PCT1

5

10

15

20

25

30

From the input data gathered, the approximate model reconstruction can be morphed into an actual three-dimensional model. Figure 5 demonstrates what a smoothed over surface can look like. Once this reconstruction is done, tools used for the surgery can be tracked with respect to this model, thereby allowing the surgeon to navigate with tools and have a reference in the body.

Once two axes have been calculated and a reference system has been established for the femur and the tibia, it is now possible to determine the cutting planes for the cut the surgeon must make of the femur bone. The cutting planes are determined in order to properly install the cutting guide on the patient. Figure 6 shows how a model of the cutting guide is displayed on the output device, along with the calculated axes and the reconstructed bone model. Using this model, the surgeon selects the position of the cutting guide. A feature displays the angle between the mechanical axis and the cutting guide allows the surgeon to reach a good level of accuracy. Some of the navigation options include sizing, cut validation, axial rotation, and preview of cuts, posterior slope, and rotation alignment. Soft tissue and gap balancing is also an option to restore the global alignment of the limb while assuring a good stability in flexion and in extension.

Figure 7 is the preferred embodiment of the registration tool to be used in the digitizing process. The tool is equipped with a position-sensing device, such as those known in the field of tracking, having three position identifying devices. In this embodiment, both ends of the tool can serve as a digitizing tip, each end having a different radius. The smaller end can be used on anatomical surfaces that do not easily accommodate the flat surface of the tool. The larger end can be used on flatter anatomical surfaces. The user selects on the computer which end is used. Alternatively, there can be automatic detection of the end being used, such as the computer recognizing the radius of the disc surface when it is placed on the bone surface. For the actual registration of the small surfaces, this can be achieved in several ways. For example, there can be a button on the tool that controls the digitizing. Alternatively, this can be done by pressing a key on a keyboard to select a point to be digitized. Also alternatively, digitizing can be triggered by a rotating action of the tool by a quarter turn. It can be appreciated that alternative embodiments for the registration tool are possible. For example, other multi-purpose combinations can be made. One end can be an awl, a 15228-168611

5

10

15

20

25

30

screwdriver, or a probe, while the other end is a digitizer. Similarly, the tool can be a single-ended digitizer as well.

The life-span of an implant or a prosthesis is dependent on the wear and tear to which it is submitted. In order to reduce the damage done to an implant over the years, it is desirable to perform soft tissue and gap balancing in the knee when placing the implant. This means the surgeon must determine the distal cut thickness of the femur such that the tendons and ligaments are not too loose or too tight so as to cause some discomfort to the patient. The thickness of the distal cut should be chosen so that the spacing between the tibia and the femur is equivalent in flexion and extension.

Figure 8 demonstrates a technique used to automatically calculate the distal cut thickness required in order to achieve soft tissue and gap balancing in the knee. A tibial cut is first made using standard techniques. The tibial cut is then validated and recorded for reference. The surgeon must then apply some pressure, either manually or using a tensor device, to the knee in order to allow the femur and tibia to return to their natural positions. The surgeon is then asked by the system to extend the leg and a measurement is taken of the distance between the tibia and the femur. The surgeon is then asked to flex the leg and another measurement is taken of the distance between the femur and the tibia. Using these two measurements, the system calculates the distal cut thickness required to provide global alignment and stability in the knee with soft tissue and gap balancing. It is desirable to have the flexion gap equal to the extension gap. The system calculates the necessary distal cut thickness required for this. The remaining cuts are done using standard techniques.

The tibia and femur each have a tracking device that is attached to the bone and moves with it, respectively. It is these tracking devices that allow the measurements of the flexion and extension gaps to be taken.

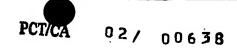
It will be understood that numerous modifications thereto will appear to those skilled in the art. Accordingly, the above description and accompanying drawings should be taken as illustrative of the invention and not in a limiting sense. It will further be understood that it is intended to cover any variations, uses, or adaptations of the invention following, in general, the principles of the invention and including such departures from the present disclosure as come within known

PCT/

02/ 00638

-7-

or customary practice within the art to which the invention pertains and as may be applied to the essential features herein before set forth, and as follows in the scope of the appended claims.



#### WHAT IS CLAIMED IS:

- 1. A method for intra-operatively presenting an approximate model of an anatomical structure by collecting a cloud of small surfaces.
- 2. A system that takes a collection of points and displays an approximate model of a surface of an anatomical structure.
- 3 A method for placing a positioning guide for total knee replacement orthopedic surgery, the method comprising:

locating the center of the femoral head;
calculating the mechanical axis;
digitizing the medial epicondyles;
calculating the epicondylar axis; and
calculating the planes required to place the cutting guide;

4. A method for achieving a symmetric flexion and extension gap in a knee operation, said method comprising:

cutting the tibia;

recording the tibial cut;

applying pressure to the joint to allow the bones to regain their original position;

measuring the spacing between the femur and tibla while in extension; measuring the spacing between the femur and tibla while in flexion; and computing the distal cut thickness.

## **ABSTRACT**

There is provided a method for intra-operatively presenting an approximate model of an anatomical structure by collecting a cloud of small surfaces. The cloud of small surfaces is gathered with a registration pointer having an adapted tip capable of making contact with the surface of an anatomical structure and registering the normal at the point of contact.

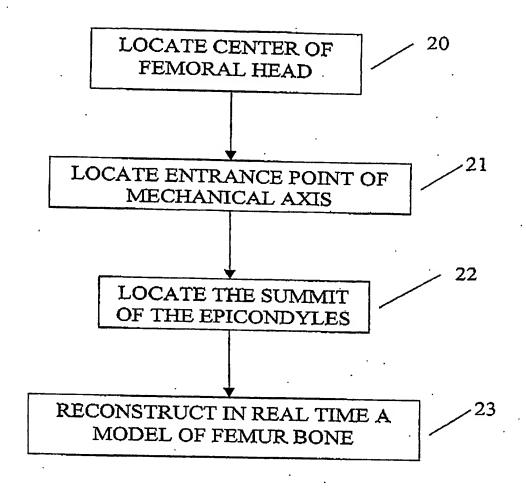


FIGURE 1

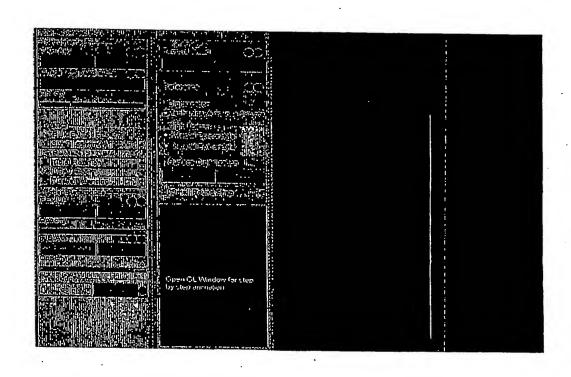


FIGURE 2

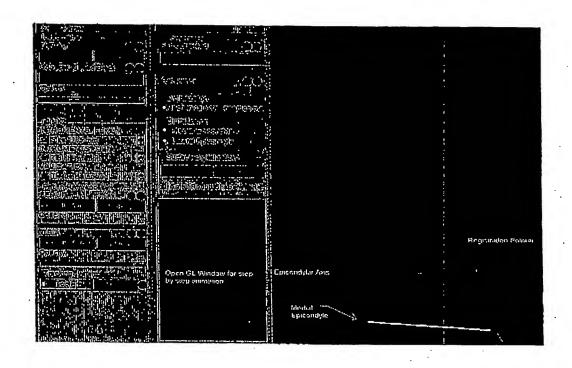


FIGURE 3

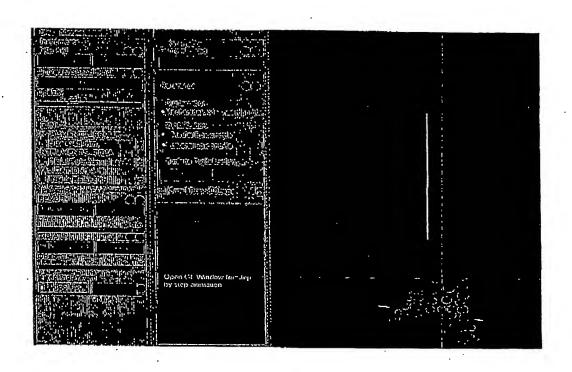
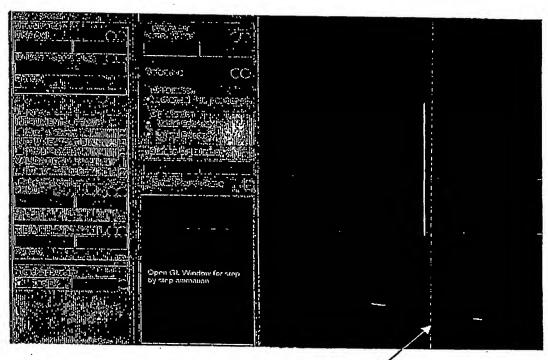


FIGURE 4



ENTRANCE POINT

FIGURE 5

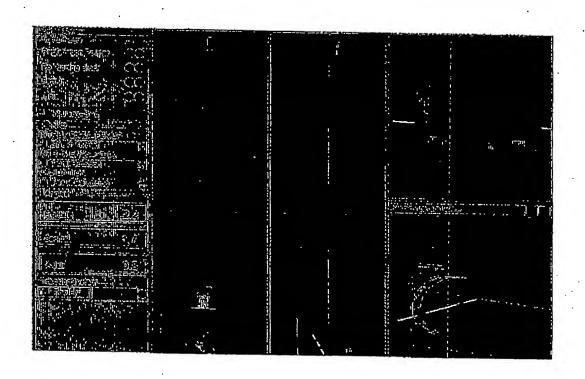


FIGURE 6.

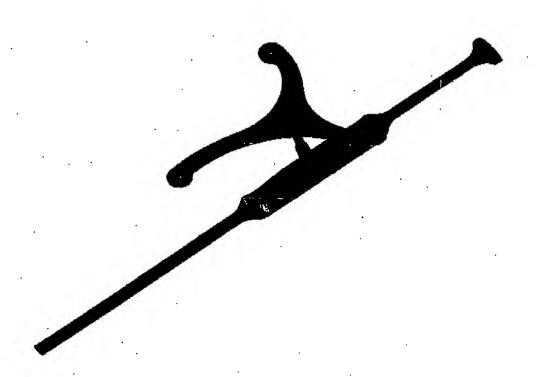


FIGURE 7

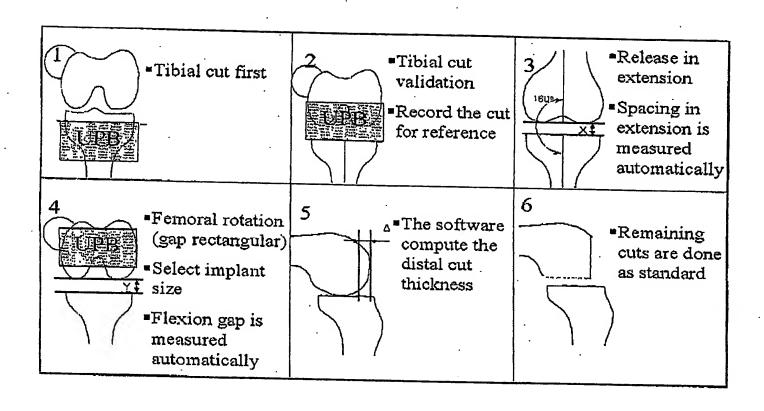


FIGURE 8

# This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☐ BLACK BORDERS
☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
☐ FADED TEXT OR DRAWING
☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
☐ SKEWED/SLANTED IMAGES
☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
☐ GRAY SCALE DOCUMENTS
LINES OR MARKS ON ORIGINAL DOCUMENT
☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
Потиев.

## IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.